

## LOUISIANA BOARD OF DRUG AND DEVICE DISTRIBUTORS

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Application for licensure as a distributor of legend drugs (including medical gases) or legend (medical) devices is required and regulated in accordance with Louisiana Revised Statutes 37:3461-3482, and Board promulgated rules in the Louisiana Administrative Code 46:XXXIV.101-1503.

*Distribution* (by distributor) means the sale or facilitation of delivery of legend drugs or legend devices to a person other than the consumer or patient, including but not limited to distribution by manufacturers, repackagers, own-label distributors, jobbers, third-party logistics providers, retail pharmacy warehouses, pharmacies, brokers, agents, and wholesale distributors.

A *legend drug or legend device* is any drug or device intended for use by humans that carries on its label "Rx", "Rx only", "Caution: Federal law prohibits dispensing without a prescription", a designation for physician use only, or a statement that federal law restricts sale by or on the order of a licensed health care practitioner.

EVERY LEGEND DRUG OR DEVICE DISTRIBUTOR WHO ENGAGES IN THE DISTRIBUTION OF THESE DRUGS OR DEVICES INTO OR WITHIN THE STATE OF LOUISIANA TO PERSONS OTHER THAN CONSUMERS OR PATIENTS MUST REGISTER WITH THE LOUISIANA BOARD OF DRUG AND DEVICE DISTRIBUTORS AND MUST RENEW SUCH LICENSE ANNUALLY.

In the case where a (owner) company utilizes a third party logistic provider (3PLP) – that is, a person that provides or coordinates warehousing, facilitation of delivery, or other logistic services for a legend drug or legend device in interstate and intrastate commerce on behalf of a manufacturer, distributor, or dispenser of a legend drug or legend device but does not take ownership of the legend drug or legend device nor have responsibility to direct the sale or disposition of the legend dug or legend device - both the owner company as the seller and the 3PLP company as the physical distributor must each be licensed.

A separate license is required for each facility or physical location directly or indirectly owned or operated by the same business entity or for a parent entity with divisions, subdivision, subsidiaries, and/or affiliate companies when operations are conducted at more than one location and there exists joint ownership and control among all the entities. A parent entity must license all divisions, subdivisions, subsidiaries, and/or affiliate companies owned by the parent company that sell and/or ship legend drugs or devices in or into Louisiana.

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